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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,635	10/25/2000	Kestutis Tautvydas	11536-001001/55190USA8A	4398

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/696,635	TAUTVYDAS ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004 and 24 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on March 22, 2004 and February 24, 2004 wherein claims 31-45 have been amended and claims 46-49 are newly submitted.

Currently, claims 31-49 are pending in this application.

Claims 31-49 are examined on the merits herein.

The following is new rejection(s) necessitated by Applicant's amendment filed March 22, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-49 as amended are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted March 22, 2004 with respect to amended claims 31-45 and new claims 46-49 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "wherein the monoester and the enhancer (comprising benzoic acid or

salicylic acid) are present in an amount effective to provide a **synergistic** antimicrobial activity..." (emphasis added). Nowhere does this limitation appear in the specification.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-49 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling the instant composition comprising a fatty acid monoester in combination with an enhancer herein, benzoic acid or salicylic acid for enhancing antimicrobial activity disclosed in the specification, does not reasonably provide enablement for a **synergistic** antimicrobial activity produced by the claimed combination of a fatty acid monoester and benzoic acid or salicylic acid.

The instant claims are drawn to an invention that the combination of a fatty acid monoester in combination with an enhancer, benzoic acid or salicylic acid, provide a synergistic antimicrobial activity.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to an antimicrobial formulation and kit.

The relative skill of those in the art: The relative skill of those in the art is high.

In regard to the following *Wands* factors, the predictability or unpredictability of the art; the amount of direction or guidance presented; the presence or absence of working examples as discussed below:

The instant claimed invention is highly *unpredictable*. Synergistic or superadditive effects for combinations of compounds are highly unpredictable. In the instant case there is insufficient guidance and **no** working examples or testing results for the claimed combination of a fatty acid monoester and benzoic acid or salicylic acid in the specification. Thus, the specification fails to demonstrate any synergistic effects produced by the combination claimed herein.

Moreover, as discussed in the previous Office Action November 11, 2003 at page 9-10, the declaration of Andrews filed September 4, 2003 under 37 CFR 1.132, is insufficient to establish the fact that the claimed combination has any unexpected

synergism as follows. First the declaration merely presents the comparable results among the compositions "A' comprising the combination of the monoester and salicylic acid, and "B" comprising combination of the monoester and benzoic acid, "C" comprising combination of the monoester and lactic acid, i.e., it is noted that all log reduction by all three compositions are merely comparable, and it is also noted even the log reduction by the water control is comparable to three composition. Secondly, these results appears generated from one shot, not from the statistic results. Thus, the accuracy, reliability and statistical validity of these results are in question.

Therefore, in view of the *Wands* factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test the claimed combination whether they produced a synergistic effect in antimicrobial, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. (5,460,833, of record) in view of Viccaro et al. (5,188,822, of record) and

Carmody (5,145,685, of record) for reasons of record stated in the Office Action dated November 11, 2003.

Andrews et al. discloses an antimicrobial composition comprising (i) the instant fatty acid monoester such as glycerol monolaurate, propylene glycol monolaurate, glycerol and propylene glycol monoesters of caprylic and capric acids in amounts within the instant claim, (ii) the instant enhancers in amounts within the instant claim further comprising a chelating agent, EDTA, and the instant organic acid such as lactic acid, tartaric acid, adipic acid, succininc acid, citric acid, and all other instant acids, (iii) a food grade surfactant, anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; and a vehicle i.e., water and/or particular alcohols: propylene glycol and polyethylene glycol, or aqueous solution and ethanol (see abstract, col.2 lines 38-55, col.3 lines 1-8 and 35-38, col.4 lines 36-62, col.5 lines 4-13 and 20-39, and claims 1-9). Andrews et al. particularly discloses the components (i), (ii) and (iii) used together in the composition therein provide a synergistic antimicrobial activity, compared to used alone under the same condition (see col.2 lines 55-57 and col.3 lines 54-57). Hence, each of three major component alone is known to have antimicrobial activity. Andrews et al. also teaches that organic acids including the acids employed therein are known antimicrobial agents (see col.1 line 67 to col.2 line 7). Andrews et al. further discloses the compositions therein prepared by mixing the ingredients in the particular order (see col.5 lines 41 to col.6 line 5).

Andrews et al. do not expressly disclose the employment of the particular organic acid, benzoic acid or salicylic acid in their antimicrobial compositions.

Viccaro et al. discloses that benzoic acid is a known antimicrobial compound and useful in the oral (dental) composition therein, having antimicrobial activity (see col.1 and col.25, claim 11).

Carmody discloses that salicylic acid is a known antimicrobial agent and useful in the skin composition therein, having antimicrobial activity (see abstract, col.10-11, claims 2 and 12).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al., since both benzoic acid and salicylic acid are known antimicrobial agents and also known to be useful in the antimicrobial compositions according to the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that employing or adding benzoic acid or salicylic acid, known useful for the same purpose, i.e., antimicrobial, in the antimicrobial composition of Andrews et al. would improve the antimicrobial effect and/or would produce additive effects for the composition of Andrews et al.

Since all active composition components herein are known to useful in antimicrobial compositions, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At

least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Moreover, the disclosure of Andrews et al. in regard to combination of (i), (ii) and (iii) in the composition therein exerting a synergistic antimicrobial activity, has further provided the motivation for employing or adding the particular organic acid benzoic acid or salicylic acid, the known antimicrobial agents, in the antimicrobial composition of Andrews et al.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Andrews et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. (5,569,461, PTO-1449 submitted January 24, 2001) in view of Viccaro et

al. (5,188,822, of record) and Carmody (5,145,685, of record) for reasons of record stated in the Office Action dated November 11, 2003.

Andrews et al. discloses an antimicrobial composition comprising (i) the instant fatty acid monoester such as propylene glycol monoesters of caprylic and capric acids in amounts within the instant claim, (ii) the instant enhancers in amounts within the instant claim further comprising a chelating agent, EDTA, and the instant organic acid such as lactic acid, tartaric acid, adipic acid, succininc acid, citric acid, and all other instant acids, (iii) anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; and a vehicle i.e., water and/or solvents miscible with water, particular alcohols: propylene glycol and polyethylene glycol, or aqueous solution , and fragrances (see abstract, col.2 lines 13-20, col.3 lines 1-56, col.4 lines 1-30, Examples at col.6, and claims 1-5). Andrews et al. particularly discloses the components (i), (ii) and (iii) used together in the composition therein provide surprisingly potent antimicrobial systems (see col. 13-19) and a synergistic antimicrobial activity, compared to used alone under the same condition (see col.2 lines 55-57 and col.3 lines 54-57). Hence, each of three major component alone is known to have antimicrobial activity. Andrews et al. also teaches that the organic acids including the acids employed therein are synergists as antimicrobial agents that may be used solely or in combination (see col.3 line 42-56). Andrews et al. further discloses the compositions therein prepared by mixing the ingredients in the order (see col.4 lines 52 to col.5 line 5).

Andrews et al. do not expressly disclose the employment of the particular organic acid, benzoic acid or salicylic acid in their antimicrobial compositions.

Viccaro et al. discloses that benzoic acid is a known antimicrobial compound and useful in the oral (dental) composition therein, having antimicrobial activity (see col.1 and col.25, claim 11).

Carmody discloses that salicylic acid is a known antimicrobial agent and useful in the skin composition therein, having antimicrobial activity (see abstract, col.10-11, claims 2 and 12).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al., since both benzoic acid and salicylic acid are known antimicrobial agents and also known to be useful in the antimicrobial compositions according to the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that employing or adding benzoic acid or salicylic acid, known useful for the same purpose, i.e., antimicrobial, in the antimicrobial composition of Andrews et al. would improve the antimicrobial effect and/or would produce additive effects for the composition of Andrews et al.

Since all active composition components herein are known to useful in antimicrobial compositions, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At

least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Moreover, the disclosure of Andrews et al. in regard to combination of (i), (ii) and (iii) in the composition therein exerting a synergistic antimicrobial activity and organic acids employed therein as being synergists used solely or in combination, has further provided the motivation for employing or adding the particular organic acid benzoic acid or salicylic acid, the known antimicrobial agents, in the antimicrobial composition of Andrews et al.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Andrews et al.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Argument

Applicant's remarks filed on March 22, 2004 and February 24, 2004 with respect to the rejections made under 35 U.S.C. 103(a) in the previous Office Action November 11, 2003 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant asserts that Table 3 and Table 4 have provided surprising results for the claimed invention. However, the tested formulations in Table 3 and 4 are **not** the claimed combination of a fatty acid monoester and benzoic acid or salicylic acid. See the tested formulations disclosed in Table 1 and 2 at 17-18 of the specification. Hence, these testing results do not involve the claimed features of the invention. Therefore, the specification fails to demonstrate any additive or synergistic effects or unexpected results produced by the combination claimed herein.

Moreover, as discussed in the previous Office Action November 11, 2003 at page 9-10, the declaration of Andrews is insufficient to establish the fact that the claimed combination has any unexpected synergism as follows. First the declaration merely presents the comparable results among the compositions "A' comprising the combination of the monoester and salicylic acid, and "B" comprising combination of the monoester and benzoic acid, "C" comprising combination of the monoester and lactic acid, i.e., it is noted that all log reduction by all three compositions are merely comparable, and it is also noted even the log reduction by the water control is comparable to three composition. Secondly, these results appears generated from one shot, not from the statistic results. Thus, the accuracy, reliability and statistical validity of these results are in question.

Thirdly, the cited prior art 5,460,833, and 5,569,461 are not limited to one acid, lactic acid or alpha-hydroxy organic acids as asserted in the declaration (see page 3 and the testing results in the declaration). Other organic acids for example acetic acid, sorbic acid, and adipic acid taught by the cited prior art (see 5,460,833 col.4 lines 45-50

and 5,569,461 col.3 lines 43-47) are not alpha-hydroxy organic acids. Thus, the evidence in the examples does not demonstrate criticality of a range of the ingredients disclosed by the prior art. See MPEP § 716.02(d).

Therefore, there is no clear and convincing evidence in the declaration and in the specification for supporting for the synergism produced by the instant combination over the prior art. Therefore, the declaration is insufficient to rebut the prima facie case herein.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
May 19, 2004

SHAOJIA ANNA JIANG
PATENT EXAMINER